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| APPLICATION NO.                                     | FILING DATE     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-----------------|----------------------|---------------------|------------------|
| 10/685,923  | 10/14/2003      | Sankar Chatterjee    | CEPH-2313           | 7061             |
| 23377   | 7590 04/27/2004 |                      | EXAMINER            |                  |
| WOODCOCK WASHBURN LLP                               |                 |                      | DESAI, RITA J       |                  |
| ONE LIBERTY PLACE, 46TH FLOOR<br>1650 MARKET STREET |                 |                      | ART UNIT            | PAPER NUMBER     |
| PHILADELPHIA, PA 19103                              |                 |                      | 1625                |                  |

DATE MAILED: 04/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | Application No.  | Applicant(s)   |  |  |  |  |
|---|--|--|--|--|--|--|
| Office Author Occurrence  | 10/685,923   | CHATTERJEE ET AL.  |  |  |  |  |
| Office Action Summary   | Examiner   | Art Unit   |  |  |  |  |
|   | Rita J. Desai  | 1625   |  |  |  |  |
| The MAILING DATE of this communication app<br>Period for Reply  | ears on the cover sheet with the   | correspondence address   |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period who Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | 36(a). In no event, however, may a reply be ti<br>within the statutory minimum of thirty (30) da<br>fill apply and will expire SIX (6) MONTHS fron<br>cause the application to become ABANDONI | mely filed ys will be considered timely. n the mailing date of this communication. ED (35 U.S.C. § 133). |  |  |  |  |
| Status  |  |  |  |  |  |  |
| 1) Responsive to communication(s) filed on  | _•   |  |  |  |  |  |
| 2a) ☐ This action is <b>FINAL</b> . 2b) ☑ This  | This action is <b>FINAL</b> . 2b) This action is non-final.  |  |  |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is  |  |  |  |  |  |  |
| closed in accordance with the practice under E  | x parte Quayle, 1935 C.D. 11, 4  | 53 O.G. 213.   |  |  |  |  |
| Disposition of Claims   |  | *  |  |  |  |  |
| 4)⊠ Claim(s) <u>1-12,14,15,20,21,25 and 26</u> is/are pending in the application.   |  |  |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.  |  |  |  |  |  |  |
| 5) Claim(s) is/are allowed.   |  |  |  |  |  |  |
| 6) Claim(s) is/are rejected.  |  |  |  |  |  |  |
| 7) Claim(s) is/are objected to.   |  | 4  |  |  |  |  |
| 8)⊠ Claim(s) <u>1-12, 14, 15, 20, 21, 25 and 26</u> are su  | bject to restriction and/or election   | on requirement.  |  |  |  |  |
| Application Papers  |  |  |  |  |  |  |
| 9) The specification is objected to by the Examiner   |  |  |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) □ acce   | epted or b) objected to by the   | Examiner.  |  |  |  |  |
| Applicant may not request that any objection to the d   | drawing(s) be held in abeyance. Se   | e 37 CFR 1.85(a).  |  |  |  |  |
| Replacement drawing sheet(s) including the correction   | on is required if the drawing(s) is ob   | pjected to. See 37 CFR 1.121(d).   |  |  |  |  |
| 11)☐ The oath or declaration is objected to by the Exa  | aminer. Note the attached Office   | Action or form PTO-152.  |  |  |  |  |
| Priority under 35 U.S.C. § 119  |  |  |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign   a) All b) Some * c) None of:  | priority under 35 U.S.C. § 119(a   | )-(d) or (f).  |  |  |  |  |
| 1. Certified copies of the priority documents have been received.   |  |  |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No  |  |  |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage   |  |  |  |  |  |  |
| application from the International Bureau   | •  |  |  |  |  |  |
| * See the attached detailed Office action for a list of   | of the certified copies not receive  | ed.  |  |  |  |  |
|   |  |  |  |  |  |  |
| Attachment(s)   |  |  |  |  |  |  |
| 1) Undice of References Cited (PTO-892)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  1) Interview Summary (PTO-413) Paper No(s)/Mail Date   |  |  |  |  |  |  |
| Paper No(s)/Mail Date   |  | Patent Application (PTO-152)   |  |  |  |  |
|   |  |  |  |  |  |  |

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## Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-12, 14,15, 25 in part, drawn to compounds wherein they have the formula given in table 2, wherein W is a Ser, Pro, Leu containing, R is a nonhetero ring and R2 is Bn, classified in class 564, 514, and various subclasses.
- II. Claims 1-12, 14, 15, 25in part, drawn to compounds and pharmaceutical compositions as given by formula in in table 2, wherein W is a Ser, Pro, Leu containing, R2 is a Bn and R is a thienyl group attached to SO2, classified in class 548 and various subclasses.
- III. Claims 1-12, 14, 15, 25 drawn to compounds and compositions as given in the formula in table 2, W is Ser. Pro, Leu containing, R 2 is a Bn and R is a pyridinyl classified in class 546, 514and various subclass.
- IV. Claims 1-12, 14, 15, 25 drawn to compounds and compositions as given in the formula in table 2, W is Ser. Pro, Leu containing, ,R and R2 is a other than in groups 1-3 classified in various classes and subclasses.
- V. Claims 20 and 21 drawn to compounds in table 4, not included in group 1- IV, wherein R het group is a morpholine, classified in class 540 and various subclasses.
- VI. Claims 20 and 21 drawn to compounds in table 4, not included in group 1- IV wherein R het. group is isooxazol, classified in 548 and various subclasses.

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- VII. Claim 20 and 21 drawn to compounds as given in table 4, not included in group 1- IV wherein the het group is a keto piperidine classified in class 546 and various subclasses.
- VIII. Claims 20 and 21 drawn to compounds in table 4, , not included in group 1-IV, wherein the R group does not include a het ring, classified in 560 and 562.
- IX. Claims 20 and 21 in part drawn to compounds and composition ,as given in table 4, not included in group 1- IV, wherein the R hetero ring is pyrrolidine classified in 549 and various subclasses.
- X. Claims 20 and 21 in part drawn to compounds, as given in table 4, not included in group 1- IV, wherein the R has a piperizine classified in class 544 and various subclasses.
- XI. Claims 20 and 21 in part, drawn to compounds as given in table 4, not included in group 1- IV, wherein R is other than as given in groups V to X, classified in various classes and subclasses.
- XII Claim 26 drawn to a method of treating. A further election of a single disclosed speices is required. This group is subject to further restriction.

The inventions are distinct, each from the other because of the following reasons:

Inventions I- XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different structural core and hence different bonding and function.

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The only common core is -NH-C- with all the different variables Q, A, m, R1, R2, R3 and Z gives rise to numerous permutations and combinations that that the scope is so broad, that a prior art reference anticipating the claims with respect to one member under 35 USC 102(b) would not render obvious the same claims under 35 USC 103a with respect to another member. The search of such a broard claim in many Classes and Subclasses is not coextensive. The Markush group objection finds basis in case law, compare In re Swenson 56 USPQ 180; In re Ruzicka, 66 USPQ 226; In re Winnek, 73 USPQ 225:. In view of the foregoing, restriction is required to the following inventions under 35 USC 121.

If applicant 's traverse on the grounds that the inventions are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the groups to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Rejoinder:-

If the compounds and composition of any of the groups 1 to IV are found to be allowable then the method claim 26 group XII with be rejoined, limited to the scope of the compounds, provided they are free from other 112 issues.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II-XII, restriction for examination purposes as indicated is proper.

A telephone call was made to Ms. Wendy Choi on 4/26/2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicants preserve their right to file a divisional on the cancelled , non elected subject matter, without prejudice in due course.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday,9:30 am to 6:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

R.D. April 26, 2004

> RITA DESAI PRIMARY EXAMINER